

CLAIMS:

1. Biocompatible implant for the treatment of defects in a living organism such as bone defects or tooth extraction wounds, comprising at least one zone of impermeability to soft tissue and/or epithelial cells in-growth, wherein said implant is made of an open porous scaffold and a membrane covering at least a part of said scaffold and being sealed to it such that said scaffold and said membrane form a single piece of matter.
2. Biocompatible implant according to claim 1, wherein said implant is also biodegradable.
3. Biocompatible implant according to claim 1 or 2, wherein said scaffold is made of a synthetic, biocompatible and biodegradable material, such as biopolymers, bio-glasses, bioceramics, more preferably calcium sulfate, calcium phosphate such as, for example, monocalcium phosphate monohydrate, monocalcium phosphate anhydrous, dicalcium phosphate dihydrate, dicalcium phosphate anhydrous, tetracalcium phosphate, calcium orthophosphate phosphate, calcium pyrophosphate, α -tricalcium phosphate, β -tricalcium phosphate, apatite such as hydroxyapatite, or polymers such as, for example, poly(α -hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarates), poly(amino acids), polysaccharides, polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or co-polymers, terpolymers thereof or blends of those polymers, or a combination of biocompatible and biodegradable materials.

4. Biocompatible implant according to any of the preceding claims, wherein said scaffold is made of fused, biocompatible, biodegradable granules selected from the group consisting of solid granules, porous granules, hollow granules, hollow granules with at least one opening in the granule, or a mixture thereof; said granules having an equivalent-diameter of about 100 μm to about 2000 μm , preferably 500 μm to 1000 μm ; and are preferably of a regular shape, such as, for example, a spherical shape; a major portion of said granules being coated with at least one biocompatible and biodegradable layer of a polymer selected from the group consisting of poly(α -hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarates), poly(amino acids), polysaccharides, polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or copolymers, terpolymers thereof, or blends of those polymers; and said polymer coating having a thickness of 1 μm to 300 μm , preferably about 5 μm to about 30 μm .
5. Biocompatible implant according to any of the preceding claims, wherein said scaffold has an open porous configuration with interconnected pores having a size of about 10 μm to about 2000 μm , preferably about 100 μm to about 500 μm .
6. Biocompatible implant according to any of the preceding claims, wherein said membrane is made of synthetic, biocompatible and biodegradable polymer selected from the group consisting of poly(α -hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarates), poly(amino acids), polysaccharides, polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or copolymers, terpolymers thereof, or blends of those polymers.

7. Biocompatible implant according to any of the preceding claims, wherein said biodegradable membrane is a polymer film, a polymer textile, a polymer fleece, a layer of fused polymer particles or a combination thereof, thus forming at least one zone of impermeability to soft tissue and/ or epithelial cells in-growth, and having a thickness of about 10 μm to about 3000 μm , preferably about 50 μm to about 1000 μm .

8. Biocompatible implant according to any of the preceding claim, wherein said biodegradable membrane is made of fused polymer particles, such as, for example, microspheres, pellets or granules, having a size smaller than about 500 μm , preferably having a size about 1 μm to 200 μm .

9. Biocompatible implant according to any of the preceding claims, wherein said membrane has a configuration such as to allow a transport of fluids and/ or molecules through the membrane, but forming a barrier against soft tissue and/ or epithelial cells in-growth into the implant.

10. Biocompatible implant according to any of the preceding claims, wherein at least a portion of the said membrane has a porous configuration, said porosity being formed by pores having sizes in the range of about 1 μm to 500 μm , preferably 5 μm to 50 μm .

11. Biocompatible implant according to any of the preceding claims, wherein said membrane comprises at least two layers, one of said layers having a barrier function against soft tissue and/ or epithelial cells in-growth in the scaffold, and a second layer, which is direct in contact with the surrounding living organism, allowing the stabilization and anchorage of soft tissue which tends to close the wound.

12. Biocompatible implant according to any of the preceding claims, wherein said membrane comprises at least one non-porous layer.

13. Biocompatible implant according to any of the preceding claims, said scaffold and/or said membrane including void spaces that are at least partially filled with at least one of air or gas, polymer, liquid, gel, or solid particles.

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14. Biocompatible implant according to any of the preceding claims, further comprising at least one biologically active substance which is integrated in said scaffold and/or in said granules and/or in a coating applied to the granules or implant and/or in said membrane and/or which is encapsulated in microspheres which are loaded into said scaffold and/or into said membrane and/or within macropores between said granules.

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15. Biocompatible implant according to any of the preceding claims further comprising at least one additive such as a plasticizer, which is integrated into said scaffold and/or into said membrane.

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16. Biocompatible implant according to any of the preceding claims, wherein an exposed surface of said biocompatible implant allows cell growth into the scaffold.

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17. Biocompatible implant according to any of the preceding claims, wherein said biocompatible implant is seeded with cells.

18. Method for the preparation of a biocompatible implant for the treatment of defects in a living organism such as bone defects or tooth extraction wounds, characterized by fusing or joining together an open porous scaffold and at least one membrane, which is preferably made of a polymer film, a polymer fleece, a layer of fused polymer particles or a combination thereof, thus, creating at the surface of the said implant at least one zone of impermeability against soft tissue and/or epithelial cells in-growth.

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19. Method according to claim 18, wherein said implant is also biodegradable.
20. Method according to claim 18 or 19, wherein said open porous scaffold and said membrane are fused together by subjecting them for a time span of at least about 3
5 seconds, typically for about 15 seconds to about 180 seconds to a pressurized CO₂ atmosphere, said CO₂ atmosphere having a pressure of about 20 bar to about 200 bar, preferably about 50 bar, at a temperature of about 10°C to about 100°C, preferably about 20°C to about 37°C.
- 10 21. Method according to claim 18 or 19, wherein said open porous scaffold and said membrane are fused together by subjecting them for a time span of at least about 10 seconds, typically of about 30 seconds to about 5 minutes to a heat treatment at elevated temperatures of about 50°C to about 220°C, preferably about 80°C to about 85°C.
- 15 22. Method according to any of claims 18 - 21, wherein after fusing together said scaffold and said membrane said membrane is subjected to a final heat treatment, preferably by exposure to an infra-red lamp or the like, at a temperature of about 100°C to about 220°C, preferably 120°C to 140°C, for a time span of about 5 s to
20 about 120 s, preferably about 20 s to 60 s.

23. Method according to any of claims 18 - 22, wherein said open porous scaffold is made of synthetic, biocompatible and biodegradable materials, such as bio-polymers, bioglasses, bioceramics, more preferably calcium sulfate, calcium phosphate such as, for example, monocalcium phosphate monohydrate, monocalcium phosphate anhydrous, dicalcium phosphate dihydrate, dicalcium phosphate anhydrous, tetracalcium phosphate, calcium orthophosphate phosphate, calcium pyrophosphate, α -tricalcium phosphate, β -tricalcium phosphate, apatite such as hydroxyapatite, or polymers such as, for example, poly(α -hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarates), poly(amino acids), polysaccharides, polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or copolymers, terpolymers thereof or blends of those polymers, or a combination of biocompatible and biodegradable materials; said open porous scaffold having an open porous configuration with interconnected pores having a size of about 10 μm to about 2000 μm , preferably about 100 μm to about 500 μm ; and said membrane being made of a synthetic, biocompatible and biodegradable polymer selected from the group consisting of poly(α -hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarate), poly(amino acids), polysaccharides, polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or copolymers, terpolymers thereof or blends of those polymers; said membrane being preferably in the form of a polymer film, a polymer textile, a polymer fleece, a layer of fused polymer particles or a combination thereof; and said membrane forming at least one zone of impermeability against soft tissue and/or epithelial cells in-growth into said implant.

24. Method according to any of claims 18 - 23, wherein said scaffold is made of fused biocompatible and biodegradable granules which are selected from the group consisting of solid granules, porous granules, hollow granules, hollow granules with at least one opening in the granule, or a mixture thereof; said granules having an
5 equivalent-diameter of about 100 μm to about 2000 μm , preferably 500 μm to 1000 μm , and referably being of a regular shape, such as, for example, a spherical shape; and a major portion of said granules being coated with at least one biocompatible and biodegradable polymer layer having a thickness of about 1 μm to about 300 μm , preferably about 5 μm to about 30 μm .

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25. Biocompatible implant for the treatment of defects in a living organism such as bone defects or tooth extraction wounds, comprising at least one zone of impermeability to soft tissue and/or epithelial cells in-growth, wherein said implant is made of a composite matrix and a membrane covering at least a part of said composite matrix and being sealed to it such that said composite matrix and said
15 membrane form a single piece of matter, said composite matrix comprising a plurality of inorganic or synthetic granules bonded or held together by a synthetic polymer matrix.

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20 26. Biocompatible implant according to claim 25, wherein said implant is also biodegradable.

27. Biocompatible implant according to claim 25 or 26, said inorganic or synthetic granules comprising at least one of biopolymers, bioglasses, bioceramics, more preferably calcium sulfate, calcium phosphate such as, for example, monocalcium phosphate monohydrate, monocalcium phosphate anhydrous, dicalcium phosphate dihydrate, dicalcium phosphate anhydrous, tetracalcium phosphate, calcium orthophosphate phosphate, calcium pyrophosphate, α -tricalcium phosphate, β -tricalcium phosphate, apatite such as hydroxyapatite, or polymers such as, for example, poly(α -hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarates), poly(amino acids), polysaccharides, polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or co-polymers, terpolymers thereof or blends of those polymers, or a combination of biocompatible and biodegradable materials.
28. Biocompatible implant according to any of claims 25 - 27, said inorganic or synthetic granules selected from the group consisting of solid granules, porous granules, hollow granules, hollow granules with at least one opening in the granule, or a mixture thereof; said granules having an equivalent-diameter of about 100 μm to about 2000 μm , preferably 500 μm to 1000 μm .
29. Biocompatible implant according to any of claims 25 - 28, said synthetic polymer matrix comprising at least one of poly(α -hydroxyesters), poly(ortho esters), poly(ether esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarates), poly(ester amides), poly(ethylene fumarates), poly(amino acids), polysaccharides, polypeptides, poly(hydroxy butyrates), poly(hydroxy valerates), polyurethanes, poly(malic acid), polylactides, polyglycolides, polycaprolactones, poly(glycolide-co-trimethylene carbonates), polydioxanones, or copolymers, terpolymers thereof, or blends of those polymers.

30. Biocompatible implant according to any of claims 25 - 29, said composite matrix having an open porous configuration with interconnected pores having a size of about 10 μm to about 2000 μm , preferably about 100 μm to about 500 μm .
- 5 31. Biocompatible implant according to any of claims 25 - 30, said composite matrix including void spaces between adjacent granules that are at least partially filled with at least one of air or gas, polymer, liquid, gel, or solid particles.
- 10 32. Biocompatible implant according to any of claims 25 - 31, said composite matrix including void spaces between adjacent granules that are filled with at least with a biologically active substance.
- 15 33. Biocompatible implant according to any of claims 25 - 32, wherein said biodegradable membrane is a polymer film, a polymer textile, a polymer fleece, a layer of fused polymer particles or a combination thereof, thus forming at least one zone of impermeability to soft tissue and/ or epithelial cells in-growth, and having a thickness of about 10 μm to about 3000 μm , preferably about 50 μm to about 1000 μm .
- 20 34. Method for the preparation of a biocompatible implant for the treatment of defects in a living organism such as bone defects or tooth extraction wounds, characterized by fusing or joining together a composite matrix comprising a plurality of inorganic or synthetic granules and a synthetic polymer matrix and at least one membrane, which is preferably made of a polymer film, a polymer fleece, a layer
25 of fused polymer particles or a combination thereof, thus, creating at the surface of the said implant at least one zone of impermeability against soft tissue and/or epithelial cells in-growth.
35. Method according to claim 34, wherein said implant is also biodegradable.